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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/010,942	12/06/2001	Guriq Basi	ELN-002	5594
959	7590	05/26/2004	EXAMINER	
LAHIVE & COCKFIELD, LLP. 28 STATE STREET BOSTON, MA 02109			NICHOLS, CHRISTOPHER J	
			ART UNIT	PAPER NUMBER
			1647	

DATE MAILED: 05/26/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/010,942

Applicant(s)

BASI ET AL.

Examiner

Christopher J Nichols, Ph.D.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 12 March 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-57,62,63,69,70 and 159-164 is/are pending in the application.
- 4a) Of the above claim(s) 42-57,63,69,70 and 159-164 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-41 and 62 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-57,62,63,69,70 and 159-164 are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 06 December 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Applicant's election with traverse of Group I (claims 1-41 and 62) in the Response and Amendment filed 12 March 2004 is acknowledged. The traversal is on the ground(s) that the search of Groups I-VI and X would be coextensive, that Group X is generic to the aforementioned Groups, and Groups XIII-XVI should be examined together as products and related methods. This is not found persuasive because Groups I-VI and X constitute separate, distinct, and independent Groups, each from one another for the reasons as set forth in the Restriction Requirement (24 September 2003). Each of the inventions of Groups I-VI and X would require a separate and non-coextensive search. Group X is a product which may be used in materially distinct methods such as biochemical assays in lieu of making the antibodies of Groups I-VI. Therefore the polypeptides of Group X are separate and distinct from the antibodies of Groups I-VI. Groups XIII-XIV and XV-XVI constitute separate, distinct, and independent Groups, each from one another for the reasons as set forth in the Restriction Requirement (24 September 2003). The products of Groups XIII and XIV can be used in methods which are independent and distinct from the methods of Groups XV and XVI for the reasons set forth in the Restriction Requirement (24 September 2003). The requirement is still deemed proper and is therefore made FINAL.

Status of Application, Amendments, and/or Claims

2. The Preliminary Amendment filed 9 July 2002 has been received and entered in full.

Specification — Sequence Rules

3. This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR 1.821(a)(1) and (a)(2). However, this application fails to comply with the requirements of 37 CFR 1.821 through 1.825 for the reason(s) set forth herein. This application discloses sequences on Figures 1, 2, 9, and 10; Table 13 & 14. Correction is required.
4. The disclosure is objected to because of the following informalities: incorrect WIPO publication number "W087/02671" (pp. 42 line 10); double underlined heading (pp. 108 line 12). Appropriate correction is required.

Claim Objections

5. Claim 62 is objected to because of the following informalities: said claim refers to non-elected claims. Appropriate correction is required.

Statutory Double Patenting

A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. 101 which states that "whoever invents or discovers any new and useful process ... may obtain a patent therefor ..." (Emphasis added). Thus, the term "same invention," in this context, means an invention drawn to identical subject matter. See *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1894); *In re Ockert*, 245 F.2d 467, 114 USPQ 330 (CCPA 1957); and *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

A statutory type (35 U.S.C. 101) double patenting rejection can be overcome by canceling or amending the conflicting claims so they are no longer coextensive in scope. The filing of a terminal disclaimer cannot overcome a double patenting rejection based upon 35 U.S.C. 101.

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6. Claims **1-41** and **62** are provisionally rejected under 35 U.S.C. 101 as claiming the same invention as that of claims 1-41 and 62 of copending Application No. 10/232,030. This is a provisional double patenting rejection since the conflicting claims have not in fact been patented.

7. Claims **1-41** and **62** are provisionally rejected under 35 U.S.C. 101 as claiming the same invention as that of claims 1-41 and 62 of copending Application No. 10/388,389. This is a provisional double patenting rejection since the conflicting claims have not in fact been patented.

Obvious-Type Non-Statutory Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

8. Claims **1-41** and **62** are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 47, 67, 69, and 70 of copending Application No. 09/724552. Although the conflicting claims are not identical, they are not patentably distinct from each other because the pharmaceutical composition comprising a humanized antibody that specifically binds to an epitope within residues 1-10 of A β of

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Application No. 09/724,552 encompasses the humanized immunoglobulin light chain and immunoglobulin heavy chain of 3D6 as instantly claimed. The Specification teaches that the 3D6 antibody binds to an epitope within residues 1-5 of A β (Example II) this falls into the ranges as claimed in Application No. 09/724,552.

9. This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

10. Claims **1-41** and **62** are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-11 and 23 of copending Application No. 10/703,713. Although the conflicting claims are not identical, they are not patentably distinct from each other because the pharmaceutical composition comprising a humanized 3D6 antibody and pharmaceutical compositions thereof of Application No. 10/703,713 encompasses the humanized immunoglobulin light chain and immunoglobulin heavy chain of 3D6 as instantly claimed. The Specification teaches that the 3D6 antibody binds to an epitope within residues 1-5 of A β (Example II) this falls into the ranges as claimed in Application No. 10/703,713.

11. This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

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12. Claims 8, 9, 21, 22, 24, 25, and 32 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

13. The term “an interchain packing residue” in claims 8 and 9 is a relative term which renders the claim indefinite. The term “an interchain packing residue” is not defined by the claims, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. The metes and bounds of the term are not clear from the Specification or the prior art.

14. The term “rare residue” in claim 8 is a relative term which renders the claim indefinite. The term “rare residue” is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. The metes and bounds of the term are not clear from the Specification or the prior art.

15. The term “unusual residue” in claim 9 is a relative term which renders the claim indefinite. The term “unusual residue” is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. The metes and bounds of the term are not clear from the Specification or the prior art.

16. The term “rare human framework residue” in claims 21, 22, 24, and 25 is a relative term which renders the claim indefinite. The term “rare human framework residue” is not defined by the claims, the specification does not provide a standard for ascertaining the requisite degree, and

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one of ordinary skill in the art would not be reasonably apprised of the scope of the invention.

The metes and bounds of the term are not clear from the Specification or the prior art.

17. The term “framework residue” in claim 32 is a relative term which renders the claim indefinite. The term “rare human framework residue” is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. The metes and bounds of the term are not clear from the Specification or the prior art.

Summary

18. No claims are allowed.

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Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to **Christopher James Nichols, Ph.D.** whose telephone number is **(571) 272-0889**. The examiner can normally be reached on Monday through Friday, 8:00 AM to 6:00 PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, **Gary Kunz, Ph.D.** can be reached on **(571) 272-0887**.

The fax number for the organization where this application or proceeding is assigned is **703-872-9306**.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at **866-217-9197** (toll-free).

Elizabeth C. Kemmerer

CJN
May 24, 2004

ELIZABETH KEMMERER
PRIMARY EXAMINER